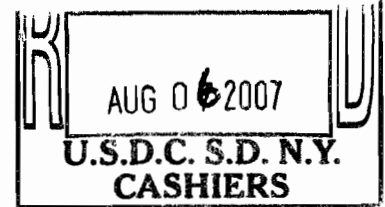


07-CV-7040

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**



STEPHEN O'GRADY, On Behalf of Himself
and All Others Similarly Situated,

Plaintiff,

v.

TELIK, INC., MICHAEL M. WICK, and
CYNTHIA M. BUTITTA,

Defendants.

**COMPLAINT FOR VIOLATION OF
THE FEDERAL SECURITIES LAWS**

CLASS ACTION

DEMAND FOR JURY TRIAL

1. This is a securities class action brought on behalf of all purchasers of the common stock of Telik, Inc. ("Telik" or the "Company") between March 27, 2003 and June 4, 2007 (the "Class Period"), including purchasers in Telik's November 5, 2003 \$172.5 million stock offering (the "2003 Offering") and Telik's January 28, 2005 \$150.9 million stock offering (the "2005 Offering"), against the Company, its Chief Executive Officer ("CEO") and Chairman of the Board, Michael M. Wick ("Wick"), its Chief Financial Officer ("CFO"), Cynthia M. Butitta ("Butitta") and the underwriters to the 2003 and 2005 Offerings for violations of the Securities Act of 1933 (the "Securities Act") and the Securities Exchange Act of 1934 (the "Exchange Act").

INTRODUCTION

2. Telik, Inc. (Nasdaq: TELK) is a biopharmaceutical company dedicated to discovering, developing and commercializing novel small molecule drugs to treat cancer and other serious diseases.

3. The Company advertises TELCYTA as its most advanced development candidate. TELCYTA (TLK286) is a cancer cell-activated chemotherapeutic that during

the class period was used in clinical trials in advanced ovarian cancer and non-small cell lung cancer.

4. When the Class Period began, Defendants had enrolled TELCYTA in late-stage clinical trials, asserting that the Company would be obtaining approval by the U.S. Food and Drug Administration (“FDA”) for the use of TELCYTA in the treatment of platinum-resistant or refractory *ovarian* cancer and later, small-cell lung cancer.

5. The primary endpoints for the TELCYTA clinical trials were the survival of a pre-designated percentage of study participants. Throughout the course of these trials, Defendants persistently claimed to be monitoring the progress of the studies. Furthermore, Defendants indicated that they would apprise the investing public of any material changes in the timing of the studies, the number of participants or any other material factors affecting the studies.

6. Contrary to their assertions, Defendants misled both the investing public and the FDA throughout the Class Period. Defendants asserted that their novel cancer treatment drug, TELCYTA, was safe and effective for public use. Furthermore, Defendants indicated that the clinical trials that they had conducted supported the safety and efficacy of this drug.

7. In fact, TELCYTA was neither safe nor effective. Defendants successfully concealed that subjects in the TELCYTA trials were dying at alarming rates and that doctors were taking patients out of the trials early, thereby compromising the data being gathered.

8. Throughout the Class Period, Defendants stated that Telik’s clinical trials were subject to the FDA’s rigorous “adequate and well-controlled” clinical trial standards. Yet, the Company’s clinical trials were haphazardly designed, poorly administered and resulted in compromised clinical data that would be unacceptable to the FDA. Defendants described the ongoing clinical trials as “robust and sophisticated” and “designed to support a successful New Drug Application (NDA) filing with the FDA for

our lead drug candidate, TELCYTA.” The Company further claimed to be monitoring enrollment levels.

9. Yet, Defendants never disclosed that in at least two arms of the final clinical trials, *up to 25% of the subjects were prematurely released from the study*. Later, Defendants would admit that another arm of the clinical trial rendered data abounding with inconsistencies. Until June 4, 2007, Defendants concealed the truth regarding TELCYTA’s toxicity and disastrous trial results.

10. As a result of the false and misleading statements regarding TELCYTA’s safety and efficacy, the price of Telik’s stock was artificially inflated during the Class Period. After the Company revealed on December 26, 2006 that TELCYTA had failed in all three arms of its final clinical testing, the Company’s stock fell from over \$16 per share to below \$5 per share – a 70% drop.

11. The Company’s stock price fell by 20% on June 4, 2007 after the Company disclosed the negative results of the ovarian cancer arm of the TELCYTA trials.

12. On June 5, 2007, after the Company had disclosed that the FDA had ordered Telik to immediately halt all TELCYTA clinical trials due to the alarming number of fatalities, the stock price dropped by 30%.

13. The Defendants knowingly concealed the following facts from the investing public during the Class Period:

- i. The final-stage clinical trials of TELCYTA were not being conducted pursuant to the FDA’s rigorous “adequate and well-controlled” clinical trial standards, rendering the resulting data meaningless;
- ii. Subjects in the TELCYTA clinical trials were experiencing higher mortality rates than those not using TELCYTA;
- iii. Defendants had reason to believe that the Company’s TELCYTA New Drug Application (“NDA”) would be rejected; and

iv. Defendants knew TELCYTA was not a commercially viable drug candidate.

14. As a result of Defendants' false and misleading Class Period statements and omissions, Telik's stock traded at inflated levels during the Class Period, trading as high as \$29.04 per share by April of 2004, whereby the Company sold over \$322 million worth of Telik stock in two underwritten public stock offerings. The Registration Statements and Prospectuses issued in connection with the 2003 and 2005 Offerings were also false and misleading, since they misstated the known safety and integrity flaws in the TELCYTA clinical trials.

JURISDICTION AND VENUE

15. This action arises under Sections 10(b) and 20(a) of the Exchange Act of 1934, as amended, 15 U.S.C. §§ 78j(b), 78(n) and 78t(a), and Securities and Exchange Commission ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder.

16. This Court has jurisdiction over this subject matter pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

17. Venue is proper in this district pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). Telik was headquartered in this district at all times relevant to this action, and many of the acts charged herein, including the dissemination of materially false and misleading information in connection with the sale of a security, occurred in this district.

18. In connection with the acts alleged in this complaint, the defendants, directly or indirectly, used means and instrumentalities of interstate commerce, including but not limited to the mails, interstate telephone and Internet communications.

PARTIES

19. Plaintiff, Stephen O'Grady, 1701 Pelham Road South, Jacksonville, AL 36265, purchased shares of Telik common stock and was damaged thereby, as reflected in the certification filed herewith.

20. Defendant Telik is located at 3165 Porter Drive, Palo Alto, California. Defendant Michael M. Wick is, and was at all relevant times, Chairman, Chief Executive Officer and President of the Company.

21. Defendant Cynthia M. Butitta is, and was at all relevant times, Chief Operating Officer (“COO”) and Chief Financial Officer of the Company.

22. Defendants Wick and Butitta are referred to herein as the “Individual Defendants.” The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Telik’s quarterly reports, press releases, and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. Each Defendant was provided with copies of the Company’s reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available, each of these defendants knew that the adverse facts specified herein were being concealed from the public and that the positive representations which were being made were materially false and misleading. The Individual Defendants are liable for the false statements pled herein, since those statements were “group-published” information, the result of the collective actions of the Individual Defendants.

CLASS ACTION ALLEGATIONS

23. Plaintiff brings this action as a class action under Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of a class of persons and entities who purchased Telik securities during the Class Period and in conjunction with the 2003 and 2005 Offerings and were damaged thereby (“the Class”). Excluded from the class are Defendants herein, officers and directors of Telik, members of their immediate families, and the heirs, successors or assigns of any of the foregoing.

24. The Class is so numerous that joinder of all members is impracticable. As of April 30, 2007, Telik had 52,459,626 shares of common stock issued and outstanding. This number was memorialized in Telik's May 3, 2007 Form 10-Q filed with the SEC.

25. Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff has no interests which are contrary to, or in conflict with, the interests of the Class members that they seek to represent. Plaintiff has retained competent counsel, experienced in class action litigation under the federal securities laws to ensure such protection, and intends to prosecute this action vigorously.

26. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy, since joinder of all members is impracticable. Furthermore, since the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation make it impossible for the members of the Class to individually seek redress for the wrongs done to them. There will be no difficulty in the management of this action as a class action.

27. Questions of law and fact common to the members of the Class predominate over any questions that may affect only individual members in that Defendants have acted on grounds generally applicable to the entire Class. Among the questions of law and fact common to the Class are:

- i. whether the Defendants' acts, as alleged herein, violated the federal securities laws;
- ii. whether Defendants' publicly disseminated releases and statements during the Class Period, omitted and/or misrepresented material facts, and whether Defendants breached any duty to convey material facts or to correct previous material misrepresentations;
- iii. whether Defendants participated in and pursued the common course of conduct complained of herein;

- iv. whether Defendants acted with scienter in omitting and/or misrepresenting material facts;
- v. whether Defendants deliberately concealed material information regarding the safety and efficacy of TELCYTA;
- vi. whether the Defendants' material misrepresentations, complained of herein, caused the market price of Telik securities to be inflated during the class period; and
- vii. whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

28. Plaintiff's claims are typical of the claims of the members of the Class as Plaintiff and members of the Class sustained damages arising out of Defendants' wrongful conduct in violation of federal law as complained of herein.

DEFENDANTS' FALSE AND MISLEADING STATEMENTS

2003

29. On March 27, 2003, Telik announced the initiation of a "Phase 3 Registration Trial of TLK286 in Ovarian Cancer Patients." The release stated that:
Telik, Inc. (Nasdaq: TELK) announced the initiation of a randomized, controlled Phase 3 registration trial of TLK 286 administered as a single agent in ovarian cancer patients whose disease has progressed following platinum-based chemotherapy and one-second line treatment.

The multinational trial, designated the ASSIST-1 (ASessment of Survival In Solid Tumors -1) trial, is expected to enroll approximately 440 women. Patients will be randomized to a TLK286 treatment group, or to a control group receiving either Doxil or Hycamtin, drugs that are commonly used in the third-line ovarian cancer setting. The study is designated to evaluate whether TLK286 treatment reduces the risk of death, leading to an increase in survival, as compared to the control group treatments.

Results from a Phase 2 single agent study of TLK286 in ovarian cancer were presented at the American Society of Clinical Oncology meeting in May 2002 and at EORTC/NCI/AACR meeting in November 2002. In this trial, objective tumor responses were observed and median patient survival was estimated at 17 months by Kaplan-Meier analysis.

"Ovarian cancer has the highest mortality rate of all gynecologic malignancies. There is an urgent need for new treatment alternatives since approximately 75% of new cases of ovarian cancer are diagnosed at an advanced

stage.," said Gail L. Brown, M.D., senior vice president and chief medical officer. *"The objective responses and survival benefit observed with TLK286 in our Phase 2 ovarian cancer trial, the clinical activity reported in other cancers, including non-small cell lung, breast and colorectal, as well as the tolerability profile seen in more than 350, provide a strong foundation for this Phase 3 trial."* (Emphasis added).

30. Wachovia Securities issued a research report based on the representations in Defendants' March 27, 2003 release and other statements by the Company. The report, entitled "Telik Initiates Pivotal Study of TLK286 in Ovarian Cancer," contained the following statements regarding TELCYTA:

Expectations for Commercialization

In addition to the Phase III ovarian cancer trial, we expect Telik to initiate a Phase III trial of TLK286 in second-line, non-small cell lung cancer (NSCLC) patients in late 2003. Based on the timing of these trials, *we estimate that TLK286 could start contributing to revenue in 2006. We estimate that nearly 9,000 patients could receive the drug in 2006, and nearly 19,000 patients could receive it in 2007. Using an estimate price of approximately \$11,000 for a course of therapy, we estimate TLK286 sales at \$98 million in 2006 and \$204.4 million in 2007. This price is consistent with current pricing on standard-of-care chemotherapy. Market penetration is estimated at 4.8% for refractory ovarian cancer patients in 2006, and 7.5% in 2007. Market penetration is estimated at 1.5% for refractory NSCLC patients in 2006 and 2.8% in 2007.* (Emphasis added)

31. The Company announced on April 9, 2003 "New Preclinical Data on TLK286 that Supports Unique Mechanism of Activation, and Activity in Combinations with Standard Cancer Drugs." This release stated that:

Telik, Inc. (Nasdaq: TELK) announced a series of preclinical studies of its TLK286 product candidate, currently in a Phase 3 registration trial for ovarian cancer, and in clinical trials in non-small cell lung, breast and colorectal cancer. The studies were published in the March 2003 Proceedings of the Annual Meeting of the American Association for Cancer Research.

TLK286 is a prodrug which is administered in an inactive form. It is activated in cancer cells by GST P1-1, an enzyme present in higher levels in important cancers including ovarian, lung, breast, colorectal, pancreas and lymphoma, than in normal tissue. In previous studies, Telik scientists have reported that TLK286 induces cancer cell death via the stress response signaling pathway. New preclinical data published on TLK286 include:

- *TLK286-induced activation of the stress response apoptotic signaling pathway: confirmation of novel antitumor mechanism of action (Abstract # 2643).* TLK286 toxicity to cancer cells increases in a time- and dose-dependent manner after it is cleaved by GST P1-1. Using an analog of

TLK286 that could not be cleaved by GST P1-1, Telik scientists demonstrated that the non-cleavable analog was inactive, and therefore that cleavage is required for TLK286 activation and subsequent cancer cell killing. This result supports the premise that the selective activation of TLK286 within cancer cells contributes to the generally mild side effect profile and antitumor activity of TLK286 seen in clinical trials.

- *Enhanced antitumor activity of TLK286 in combination with oxaliplatin, carboplatin, doxorubicin, paclitaxel and docetaxel in human colorectal, ovarian, non-small cell lung and breast cancer cell lines (Abstract # 1722).* Human cancer cell lines were treated with TLK286 in combinations with several important chemotherapeutic drugs. The studies consistently demonstrated enhanced or synergistic cancer cell growth inhibition. For example, treatment of a colorectal cancer cell line with TLK286 and oxaliplatin resulted in a fifteen-fold increase in growth inhibition compared to the sum of either agent alone. These data, and the mild, non-overlapping toxicities seen in clinical trials of TLK286, suggest that combinations may be appropriate and provide scientific support for ongoing clinical trials using TLK286 in regimens with docetaxel, carboplatin and doxorubicin (Doxil®).

- *Sensitization of a human cancer cell line to paclitaxel following prolonged treatment with TLK286 (Abstract # LB123).* Following up on the combination studies, Telik scientists examined the effects of prolonged exposure of human ovarian cancer cells to TLK286. TLK286 exposure was associated with enhanced sensitivity of the cancer cells to taxanes, an important class of chemotherapeutic drugs.

32. On April 24, 2003, Telik announced its first quarter 2003 financial result in a press release. The release stated in relevant part:

Key developments at Telik since the beginning of 2003 have included:

- The initiation of a Phase 3 registration trial of TELCYTA in ovarian cancer patients whose disease has progressed following platinum-based chemotherapy and one second-line treatment. The multinational trial, designated ASSIST -1 (ASessment of Survival In Solid Tumors - 1) trial is designed to evaluate whether TELCYTA treatment reduces the risk of death, leading to an increase in survival, as compared to the control group treatments.
- The publication of new preclinical data that support the ongoing clinical development of TELCYTA. These data elaborate on the proposed mechanism of activation and activity of TELCYTA and describe the use of TELCYTA in combination with standard chemotherapeutic drugs.

33. During a presentation at the American Society of Clinical Oncology ("ASCO") on May 31, 2003, the Company stated that its in-progress follow-up trial on advanced lung-cancer patients treated with TELCYTA confirmed earlier data that the

drug increased survival time. This Phase II two involved non-small cell lung-cancer patients who had failed two or more previous therapies. Additionally, these patients had life expectancies ranging only from 4.5 months to 6.5 months. Telik's Senior Vice President and Chief Medical Officer reported that 81% of the 33 patients enrolled in the trial were still alive. Telik also presented these additional findings:

- “*Ovarian cancer*: New interim clinical results *confirmed* the significant clinical activity reported in the previous Phase 2 clinical trial of TELCYTA in women with advanced ovarian cancer, and supported the ongoing Phase 3 trial in this potential indication.”
- “*Non-small cell lung cancer*: Interim results from a second Phase 2 clinical trial in poor prognosis patients who have failed platinum-containing regimens *confirmed* the results reported in the prior Phase 2 clinical trial in non-small cell lung cancer, *in which disease stabilization was associated with a median survival that was significantly improved over that expected for these patients.*”
- “In these clinical trials, as in the previous clinical trials, TELCYTA treatment was well-tolerated with most side effects mild and reversible.” Defendants stated there were few “grade 1” and “grade 2” side effects and no “grade 3” or “grade 4” events experienced.
- Telik “plan[ed] to initiate a registration Phase 3 Trial of TELCYTA for the treatment of advanced non-small cell lung cancer.”

34. On June 1, 2003, the Company announced “Confirmatory Results from Second Phase 2 Trial of TELCYTA in Advanced Non-Small Cell Lung Cancer.” The release stated in relevant part that:

Telik, Inc. announced positive interim results from a second Phase 2 trial which confirm the clinical activity of TELCYTA (TLK286) administered as a single agent in the treatment of patients with non-small cell lung cancer who have failed platinum-containing regimens. The data were presented at the annual meeting of the American Society of Clinical Oncology in Chicago.

Interim results from this trial show an 8% objective response rate (one partial response by the RECIST criteria), one minor response (8%) and a 67% overall disease stabilization rate. Median duration of stable disease is greater than 4.5 months and ongoing. Median survival has not yet been reached. TELCYTA continues to be well-tolerated, with the most common adverse events in this trial categorized as Grade 1 or 2 (mild to moderate). There were few Grade 3 and no

Grade 4 adverse events. Thirty-three patients with Stage IIIB of IV non-small cell lung cancer were evaluable for survival and 12 patients were evaluable for tumor response at the time of interim analysis. Half had failed prior platinum therapy and two-thirds also were resistant to paclitaxel.

“Advanced, chemotherapy-resistant non-small cell lung cancer patients have a predictably poor prognosis, and published clinical trials with second- and third-line agents for the disease have shown low response rates and median survival times from four to six months,” said Gail L. Brown, M.D., senior vice president and chief medical officer. “In the earlier Phase 2 trial of TELCYTA in non-small cell lung cancer, median survival was significantly improved over that expected for these patients. We are encouraged that the objective responses and high disease stabilization rate may translate to a survival advantage in this ongoing trial.”

Telik plans to initiate a registration Phase 3 trial of TELCYTA for the treatment of advanced non-small cell lung cancer.

In Phase 2 trials, TELCYTA has demonstrated clinical activity in ovarian, breast and colorectal cancer, in addition to non-small cell lung cancer. A high proportion of these tumors express GST P1-1, which activates TELCYTA within the tumor.

35. On June 2, 2003, Telik issues a release entitled “Telik’s TELCYTA (TLK286) Demonstrates Significant Clinical Activity in Advanced Metastatic Breast Cancer.” The release stated in relevant part:

Telik, Inc. announced positive interim results from the first Phase 2 study of TELCYTA (TLK286) in the treatment of women with advanced metastatic breast cancer. The data were presented at the annual meeting of the American Society of Clinical Oncology in Chicago.

There was a 15% objective response rate (one complete response and two partial responses by RECIST criteria), and a 35% overall disease stabilization rate in this poor prognosis patient group. Median duration of stable disease is greater than 4 months and ongoing. TELCYTA continues to be well-tolerated, with the most common adverse events in this trial categorized as Grade 1 or 2 (mild to moderate). There were few Grade 3 and no Grade 4 adverse events.

The interim analysis is based on 40 women with Stage IV metastatic breast cancer, 20 of whom were evaluable for tumor response at the time of interim analysis. All of the patients had failed two or more prior therapies including anthracyclines and taxanes. Most of the patients have disease that had metastasized to two or more organ systems.

“We have for the first time demonstrated responses to TELCYTA in advanced metastatic breast cancer, in women who have exhausted essentially all treatment alternatives,” said Gail L. Brown, M.D., senior vice president and chief medical officer. “*The interim results of this trial, including objective complete*

and partial responses, support further testing of TELCYTA in advanced breast cancer, a very difficult to treat cancer, as a single agent as well as in combination regimens in less advanced patients.” (emphasis added)

In Phase 2 trials, TELCYTA has demonstrated clinical activity in ovarian non-small cell lung and colorectal cancer, in addition to breast cancer. A high proportion of these tumors express GST P1-1, which activates TELCYTA within the tumor.

36. In response to the positive news regarding Telik made on May 31, 2003 and June 2, 2003, the price of Telik shares rose \$1.44 to over \$16 per share on June 2, 2003. This represents a 9.5% increase in price.

37. Following the release of the aforementioned news, Defendant Wick made a number of presentations to various groups in June 2003, which the Company later webcasted from their website. These presentations included:

- A June 5, 2003 presentation at Needham's Biotechnology Conference in NYC.
- A June 18, 2003 presentation at the Thomas Weisel Partners Growth Forum in Santa Barbara, CA.
- A June 25, 2003 presentation at the Wachovia Securities Conference on Nantucket.

38. The Company announced in second quarter financial results in a press release on July 20, 2003. The release stated in relevant part that:

At the annual meeting of the American society of Clinical Oncology (ASCO) in May 2003, Telik reported positive new interim results from Phase 2 clinical trials of TELCYTA in ovarian, non-small cell lung and breast cancer. Key findings included:

Ovarian cancer: New interim clinical results confirmed the significant clinical activity reported in the previous Phase 2 clinical trial of TELCYA in women with advanced ovarian cancer, and support the ongoing Phase 3 trial in this potential indication.

Non-small cell lung cancer: Interim results from a second Phase 2 clinical trial in poor prognosis patients who failed platinum-containing regimens confirmed the results reported in the prior Phase 2 clinical trial in non-small cell lung cancer, in which disease stabilization was associated with a median survival that was significantly improved over that expected for these patients.

* * *

In these clinical trials, as in the previous clinical trials, TELCYTA treatment was well tolerated, with most side effects mild and reversible.

39. The Company held an earning conference call on July 30, 2003 during which Defendant Wick stated that the “strict, independently verified response criteria” being employed in the ovarian cancer arm of the studies were typically reserved only for use in Phase III trials, but that they were being employed in this Phase II trial as part of the Company’s *“strategy of reducing risks going forward by conducting Phase 2 trials to Phase 3 standards.”* Defendants also stated that the Company’s quarterly cash burn would increase to between \$55 and \$60 million per quarter when the Phase III ovarian study began. (emphasis added)

40. Telik issued a release on August 14, 2003 entitled “Telik Announces Positive Follow-Up Results from Phase 2 Trial of TELCYTA in Advanced Non-Small Cell Lung Cancer.” The release confirmed the data presented at the May 3, 2003 ASCO meeting.

41. On September 3, 2003, the Company announced that it had received “FDA Fast Track Designation” for TELCYTA for the treatment of ovarian cancer. The press release stated that *“Fast Track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.”*

42. Following the release of the aforementioned news, Defendant Wick made a number of presentations to various groups in September and October of 2003, which the Company later webcasted from their website. These presentations included:

- A September 4, 2003 presentation at the Thomas Weisel Partners Healthcare Tailwinds 2003 Conference in Boston.
- A September 5, 2003 presentation at Bear Stearns’ 16th Annual Healthcare Conference in NYC.

- A September 19, 2003 presentation at USB's Global Life Sciences Conference in NYC.
- An October 21, 2002 presentation at Rodman & Renshaw Techvest Healthcare Conference in Boston.

43. On October 1, 2003 Telik announced the successful completion of FDA Special Protocol Assessment review TELCYTA for the treatment of lung cancer in the ASSIST-2 trial.

44. The Company announced its third quarter financial results for 2003 on October 29, 2003. The announcement stated in relevant part that:

- The Phase 3 clinical trial protocol for TELCYTA in advanced non-small cell lung cancer (NSCLC) has successfully completed Special Protocol Assessment (SPA) review by the U.S. Food and Drug Administration. The protocol for the ongoing Phase 3 TELCYTA trial in platinum refractory or resistant ovarian cancer previously underwent successful SPA review.
- Telik received FDA Fast Track designation for TELCYTA for third-line treatment in patients with platinum refractory or resistant ovarian cancer.
- Telik reported maturing results from a Phase 2 trial of TELCYTA on advanced non-small cell lung cancer at the Tenth World Conference on Lung Cancer. The results demonstrated an 11% objective response rate and 69% overall disease stabilization rate.
- Telik reported interim data from three Phase 1-2a clinical trials in which TELCYTA was used in combination with standard chemotherapy drugs. *Results indicate that the combinations were well tolerated at all doses tested.* In the carboplatin combination trial in heavily pretreated, third-line or greater patients who had failed a platinum-containing regimen, five of either evaluable patients (63%) had objective tumor responses by the RECIST criteria, including one complete response, and an 88% overall disease stabilization rate was observed. In the docetaxel combination trial in second and third-line non-small cell lung cancer patients, three of 14 evaluable patients (21%) who received full doses of TELCYTA and docetaxel had objective tumor responses by the RECIST criteria, and the overall disease stabilization rate was 64%. In combination with Doxil, the combination resulted in a 33% objective response rate by the RECIST criteria and 100% disease stabilization rate among the three evaluable ovarian cancer patients treated with the highest dose of each drug.

45. On October 29, 2003, Defendants announced that the Company would offer six million shares of stock in an equity offering. This Offering was a "shelf

registration.” As such, after the Prospectus was declared effective, Telik’s filings with the SEC would be automatically “incorporated by reference. Telik would issue and sell five million shares of the stock, and Sanwa Kagaku, one of Telik’s early venture backers would sell one millions shares of previously issued stock. UBS, Lehman, Bear Stearns, Needham, Lazard and Fortis would underwrite the offering.

46. Telik announced its Registration Statement had been declared effective on November 6, 2003. The Company priced the 2003 Offering at \$20 per share. 8.625 million shares in total, with the underwriter’s allotment of additional shares, would be sold in the 2003 Offering for total gross proceeds of \$172.5 million.

47. Filed in connection with the 2003 Offering, the Prospectus stated that TELCYTA had the ability to “bind to GST P1-1 inside a cancer cell” and thereby cause a “chemical reaction [to] occur, releasing fragments of TELCYTA *that cause[d] programmed cancer cell death or apoptosis.*”

48. This statement was materially false and misleading when made because Defendants concealed the fact that patients had experienced high levels of side effects during the drug’s Phase II testing.

49. Filed in connection with the 2003 Offering, the Prospectus stated that Telik had “initiated a Phase 3 registration trial of TELCYTA for the treatment of ovarian cancer in March 2003.”

50. This statement was materially false and misleading when made because the ASSIST-1 study that was currently taking place was not “adequate and well controlled,” as had been represented. The results of this study would subsequently not be accepted by the FDA as “substantial evidence” of TELCYTA’s efficacy.

51. Filed in connection with the 2003 Offering, the Prospectus stated that “[r]esults from . . . trials [evaluating more than 400 cancer patients in 12 clinical trials] indicat[ing] that TELCYTA [was] generally well tolerated, with mostly mild to moderate side effects.

52. This statement was materially false and misleading when made because the subjects in Phase II testing had actually experienced very high levels of side effects.

53. Filed in connection with the 2003 Offering, the Prospectus stated that in “June 2003, at the American Society of Clinical Oncology annual meeting, [the Company] announced positive interim results from the multimember Phase 2 trials of TELCYTA in ovarian, non-small cell lung . . . cancer.” It also stated that TELCYTA demonstrated “significant single agent antitumor activity, including multiple objective tumor responses and prolongation of expected survival in patients who were unresponsive to standard treatments” in the ovarian cancer trial.

54. This statement was materially false and misleading when made because the subjects in the Phase II testing had actually experienced very high levels of side effects.

55. Filed in connection with the 2003 Offering, the Prospectus stated that the Company had a plan “to develop product candidates with a clear path to regulatory approval and the potential to show *early evidence of clinical efficacy*. This would allow Telik to “reduce the risk inherent in drug discovery and accelerate the commercialization of [its] drug candidates.”

56. This statement was materially false and misleading when made because not only were the patients subject to the Phase II testing experiencing very high levels of side effects, but the concurrent ASSIST-1 trial was not being conducted in an “adequate and well controlled” fashion, as would be required to be acceptable to the FDA.

57. Defendant Wick gave a presentation on November 11, 2003 at the 2003 Credit Suisse First Boston Health Care Conference in Phoenix, AZ. Subsequent to the presentation, Telik’s website broadcast the presentation via webcast.

58. On December 2, 2003, Telik announced that it had received “FDA Fast Track Designation” for TELCYTA for the treatment of non-small cell lung cancer. The release stated in relevant part:

Telik, Inc. announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for TELCYTA (TLK286) for third line therapy for locally advanced or metastatic non-small cell lung cancer. The FDA previously granted Fast Track designation for TELCYTA for third line therapy in patients with platinum refractory or resistant ovarian cancer.

Fast Track programs are designed to facilitate the development and expedite the review of new drugs that demonstrate the potential to treat serious or life-threatening conditions and address unmet medical needs.

2004

59. Following the release of the aforementioned news, Defendant Wick made a number of presentations to various groups in early 2004, which the Company later webcasted from their website. These presentations included:

- A presentation at the Piper Jaffray Health Care Conference in NYC.
- A presentation at the Merrill Lynch Global Pharmaceutical, Biotechnology and Medical Device Conference in NYC.
- A presentation at Lehman's Global Healthcare Conference in Miami Beach, FL.

60. The Company announced its fourth quarter and year-end 2003 financial results in a press release on February 19, 2004. The release stated "highlights during 2003" as including:

- Telik reported positive, confirmatory results from additional Phase 2 studies of TELCYTA administered as a single agent in ovarian and non-small cell lung cancer at the American Society of Clinical Oncology meeting in June.
- Also, at the ASCO meeting, Telik reported positive preliminary data from the first clinical trial of TELCYTA in advanced metastatic breast cancer. An extension of this trial is in progress in women with metastatic breast cancer who have not previously received chemotherapy.
- The Phase 3 registration trial of TELCYTA in ovarian cancer was initiated. The trial is designed to enroll approximately 440 women with platinum refractory or resistant ovarian cancer who have also failed treatment with one of the approved second line agents.

- A Phase 3 registration trial of TELCYTA in platinum resistant non-small cell lung cancer was announced and is scheduled to begin in the current quarter.
- The protocols for the TELCYTA Phase 3 registration trials were reviewed by the FDA under Special Protocol Assessments, and the FDA granted Fast Track status for TELCYTA for the treatment of ovarian and non-small cell lung cancer in the third line setting.
- Positive interim clinical results were reported using TELCYTA in combination treatment regimens with carboplatin, Taxotere and Doxil, drugs that are used in current front line and second line chemotherapy.

61. The Company held an earnings conference call following the release.

During the call, Defendants Wick and Butitta made the following statements:

- Wick assured investors that in the Company's earlier trials of TELCYTA, the Company had "attempted to reduce development risks by conducting nine successful Phase II trials in four indications."
- Wick assured investors that TELCYTA had been measured "against a high hurdle in order to estimate its realistic potential early in the development process."
- Wick explained that earlier testing had been designed to ensure that "whatever positive effects observed could be attributed to TELCYTA, and whatever negative effects observed were also due to TELCYTA."
- Wick asserted that "TELCYTA [was] very well tolerated across all of [the Company's] trials," with the "principle toxicities [being] mild to moderate."
- Wick stated that the Phase II trials had been "designed . . . with all the bells and whistles" and that they had "built in every opportunity to have success."
- Wick stated that the Company would "*communicate with Wall Street*" if any issues arose with the trials as they moved along.
- Butitta stated that the Company was increasing spending to \$90-\$95 million for fiscal 2004 to "reflect [the Company's] enthusiasm about the potential for TELCYTA . . . and [the Company's] belief in [it] as [a] near-term growth driver for the company."
- Butitta indicated that TELCYTA's clinical activity had been demonstrated in "refractory and resistant cancer[s]."

62. On April 29, 2004, the Company issued its first quarter 2004 financial results. The release stated that "highlights since the beginning of 2004 have included":

- The ASSIST-2 trial, a multi-national Phase 3 registration trial of TELCYTA in non-small cell lung cancer (NSCLC), was initiated as planned. The trial is expected to enroll approximately 520 patients who are being randomized to TELCYTA treatment or to a control group receiving Iressa, the approved third-line treatment for NSCLC.
- A Phase 1-2a clinical trial was initiated to evaluate the combination of TELCYTA and cisplatin in NSCLC patients who have not previously received chemotherapy.
- At the American Association of Cancer Research (AACR) 94th annual meeting, preclinical data were presented demonstrating that TELCYTA demonstrated synergy, or enhanced inhibition of cancer cell growth, in combination with a number of chemotherapeutic drugs, including platinum, taxanes, anthracyclines and EGFR targeted drugs.
- Also at the AACR meeting, data were reported showing that, in preclinical models, TELCYTA is non-cross resistant with taxanes, and that TELCYTA is capable of re-sensitizing cancer cells to taxanes after resistance is established.

63. The Company held an earnings conference call following the release.

During the call, Defendants Wick and Butitta made the following statements:

- Wick again stated that “[a]cross the trials, TELCYTA ha[d] demonstrated significant anti-tumor activity, continued outstanding tolerability, and a favorable impact on survival, compared to expected, in those very advanced patients.”
- Wick assured investors that the “very strong data” received thus far in the clinical trials would permit “the attendant acceleration of market opportunity and revenue.”
- Wick stated that because the trials were “state-of-the-art” with all the “bells and whistles,” including “interim looks” and “independent data safety monitoring boards,” defendants would be able to “communicate with the street if any of those interim looks change in a material way or [the Company’s] guidance for that trial, either in terms of size, or timing, or [expected] finish” changed, and that “so far, none of those ha[d] occurred.”
- Butitta stated that the Company predicted filing an NDA for TELCYTA with the FDA in the “second half of ’05.”

64. Following the release of the aforementioned news, Defendant Wick made a number of presentations to various groups in May and June of 2004, which the Company later webcasted from their website. These presentations included:

- A presentation by Telik's officers at Fortis's Annual Biotechnology Conference in London on May 4, 2004.
- A presentation by Telik's officers at Goldman Sachs 25th Annual Healthcare Conference on June 8, 2004.
- A presentation by Telik's officers at the Pacific Growth Equities Life Sciences Conference in San Francisco on June 10, 2004.
- A presentation by Telik's officers at the Thomas Weisel Partners Growth Forum 6.0 in Laguna Nigel, CA on June 15, 2004.
- A presentation by Telik's officers at Needham's Annual Biotechnology Conference in NYC.

65. On August 5, 2004, the Company announced its second quarter 2004 financial results. The release stated that "highlights of the 2004 second quarter included":

- **American Society of Clinical Oncology (ASCO) Annual Meeting:** At the ASCO meeting in June, Telik reported positive results from three Phase 2 trials of TELCYTA used in combination with standard chemotherapy; TELCYTA plus carboplatin in platinum refractory or resistant ovarian cancer; TELCYTA plus liposomal doxorubicin in platinum refractory or resistant ovarian cancer; and TELCYTA plus docetaxel in platinum resistant NSCLC.
- **Phase 2 TELCYTA trial in front-line NSCLC:** Telik announced the initiation of a Phase 2 trial to evaluate TELCYTA in combination with carboplatin and paclitaxel in the front-line treatment of Stage IIIb or IV NSCLC. The trial is being conducted at teaching affiliates of the Harvard Medical School including the Dana-Farber Cancer Institute, Massachusetts General Hospital and Beth Israel Deaconess Medical Center. Thomas Lynch, M.D., Medical Director, Center for Thoracic Cancers, Massachusetts General Hospital and Associate Professor of Medicine, Harvard Medical School, is Principal Investigator of the study.

66. Following the release of the aforementioned news, the Company made a number of presentations to various groups in September 2004, which the Company later webcasted from their website. These presentations included:

- A presentation by Telik officers at the Thomas Weisel Healthcare Tailwinds 2004 conference in Boston on September 8, 2004.
- A presentation by Telik officers at Bear Stearns' Healthcare Conference in NYC on September 14, 2004.
- A presentation by Telik officers at USB's Global Life Sciences Conference in NYC on September 28, 2004.

67. On November 4, 2004, the Company announced its third quarter financial results. The release stated that "highlights since the beginning of the 2004 third quarter have included":

10th Biennial International Gynecological Cancer Society (IGCS) Meeting:

Telik reported data from two positive Phase 2 clinical trials of TELCYTA administered in combination with standard chemotherapy in platinum refractory or resistant ovarian cancer. The results included:

- TELCYTA plus carboplatin in platinum refractory or resistant ovarian cancer: a total of 53 patients have been enrolled in the trial, 27 of whom were evaluable for efficacy at the time of analysis. The objective response rate by RECIST is 54%, including 4 durable complete responses and 10 partial responses that have been independently reviewed. Objective responses were observed at all participating institutions including the Massachusetts General Hospital, Dana-Farber Cancer Institute and University of Texas M.D. Anderson Cancer Center. Based on these data, Telik plans to initiate the ASSIST-3 Phase 3 trial, to evaluate the combination of TELCYTA plus carboplatin versus Doxil in the second line treatment of platinum refractory or resistant ovarian cancer.
- TELCYTA plus Doxil in platinum refractory or resistant ovarian cancer: a total of 51 patients have been enrolled in the trial, including 12 treated in a separate dose-escalation phase. At the time of analysis, 19 patients in Phase 2 were evaluable for efficacy. The objective response rate by RECIST is 42%, with eight partial responses that have been independently reviewed.

68 Following the release of the aforementioned news, the Company made a number of presentations to various groups in November 2004, which the Company later webcasted from their website. These presentations included:

- A presentation by Telik officers at CSFB's Healthcare Conference in Phoenix, AZ on November 17, 2004.
- A presentation by Telik officers at Lazard's First Annual Life Sciences Conference in NYC on November 30, 2004.

69. On December 28, 2004, the Company announced that enrollment in ASSIST-1 was complete and that enrollment in ASSIST-3 was commencing.

2005

70. On January 24, 2005, Defendants announced that the Company would conduct an underwritten offering of five million shares of its stock which was priced on January 28, 2005 at \$18.75 per share when the Company's Registration Statement was declared effective. This offering was a "shelf registration." As such, after the Prospectus was declared effective, Telik's filings with the SEC would be automatically "incorporated by reference." Over eight million shares were ultimately issued and sold with the underwriters' over-allotment of shares. Thus, the 2005 Offering grossed proceeds of \$150.9 million. UBS, JP Morgan and Lehman were underwriters in the 2005 Offering.

71. Filed in connection with the 2005 Offering, the Prospectus stated that "[w]hen TELCYTA binds to GST p1-1 inside a cancer cell, a chemical reaction occurs, releasing fragments of TELCYTA that *cause programmed cancer cell death*, or apoptosis." (emphasis added)

72. This statement was materially false and misleading when made because Defendants concealed that patients had experienced high levels of side effects during the drug's Phase II testing.

73. Filed in connection with the 2005 Offering, the Prospectus stated that TELCYTA had "shown clinical antitumor activity alone and in combination in multiple Phase 2 clinical trials in refractory or resistant ovarian, non-small cell lung, breast and colorectal cancer."

74. This statement was materially false and misleading when made because Defendants concealed that patients had experienced high levels of side effects during the drug's Phase II testing.

75. Filed in connection with the 2005 Offering, the Prospectus stated that "[r]esults from these clinical trials indicate that TELCYTA is generally well-tolerated, with mostly mild to moderate side effects."

76. This statement was materially false and misleading when made because Defendants concealed that patients had experienced high levels of side effects during the drug's Phase II testing.

77. Filed in connection with the 2005 Offering, the Prospectus stated that the Company's "strategy" was to "develop product candidates with a clear path to regulatory approval and the potential to show early evidence of clinical efficacy," allowing Telik to "reduce the risk inherent in drug discovery and accelerate the commercialization of [its] drug candidates."

78. This statement was materially false and misleading when made because not only were the patients subject to the Phase II testing experiencing very high levels of side effects but also, the ASSIST-1 trial, concurrently proceeding, was not being conducted in an "adequate and well controlled" fashion, as would be required to be acceptable to the FDA.

79. On February 24, 2005, the Company announced its fourth quarter and 2004 year end financial results. The release stated in relevant part that:

At December 31, 2003, Telik had \$138.6 million in cash, cash equivalents and investments including restricted investments, compared to \$201.1 million at December 31, 2003. In February 2005, the company completed a follow-on public offering of 8,050,000 shares of its common stock resulting in gross proceeds to the company of \$150,937,500. Highlights during 2004 included:

- Enrollment was completed in the ASSIST-1 Phase 3 clinical trial of TELCYTA for third-line platinum refractory or resistant ovarian cancer.
- The ASSIST-2 Phase 3 clinical trial of TELCYTA was initiated for third-line platinum resistant non-small cell lung cancer.
- A third Phase 3 clinical trial, ASSIST-3, was initiated using the combination of TELCYTA plus carboplatin for second-line platinum refractory or resistant ovarian cancer.
- Positive results from three Phase 2 clinical trials for TELCYTA in combination with standard chemotherapy in ovarian and non-small cell lung cancer were reported at the American Society of Clinical Oncology annual meeting. Additionally positive data from the ovarian cancer trials were reported at the International Gynecologic Cancer Society meeting.
- Two additional Phase 2 clinical trials were initiated for TELCYTA, in the treatment of advanced non-small cell lung cancer patients who have not previously received chemotherapy. One of the trials is in combination with cisplatin, and the other is in combination with carboplatin and paclitaxel.
- Preclinical results that support the advancement of TELCYTA clinical developments to front-line and second-line treatment settings were reported at the American Association for Cancer Research annual meeting.

80. On May 5, 2005, Telik officers made a presentation at Defendant Lehman's Global Healthcare Conference in Miami Beach, FL. Telik later webcasted the events from its website.

81. On May 5, 2005, the Company announced its financial results for the first quarter of 2005. The release stated that “recent highlights include TELCYTA preclinical presentations at the 96th annual meeting of the American Association for Cancer

Research:

- Telik scientists reported that the combination of TELCYTA and carboplatin showed synergistic inhibition of cancer cell proliferation in vitro in both platinum resistant and platinum sensitive human ovarian cancer cells. These studies support the ongoing Phase 3 ASSIST-3 registration trial, in which the combination of TELCYTA and carboplatin is being evaluated in platinum refractory or resistant ovarian cancer in the second line setting.
- Studies were presented that describe the synergistic effects of doublet and triplet combinations of TELCYTA with platinum and taxane drugs as compared to the individual agents in human ovarian and non-small cell lung cancer cells. These data provide support for the two ongoing Phase 2 TELCYTA trials in the first line treatment of advanced non-small cell lung cancer. One trial is evaluating the combination of TELCYTA, carboplatin and paclitaxel. The second trial is evaluating the combination of TELCYTA and cisplatin. Preliminary data from the Phase 2 trials will be reported at the annual meeting of the American Society of Clinical Oncology (ASCO) later this month.
- A third report provided details on the TELCYTA-induced effects on cell cycle progression and apoptosis, or programmed cell death, consistent with its novel mechanism of targeted activation.
- In addition, Telik announced a collaboration with Stuart Aaronson, M.D., Professor and Chair, Oncological Sciences and Professor of Medicine at the Mount Sinai School of Medicine, and colleagues, to utilize Telik’s proprietary TRAP drug discover technology to discover and evaluate novel, pharmaceutically active small molecules for new cancer targets. This is one in a series of TRAP collaborations Telik has entered into with leading cancer research institutions to add to its pipeline of cancer drug candidates while expanding utilization of its TRAP technology.

82. On August 4, 2005, the Company announced its second quarter financial results for 2005. During the subsequent conference call, Defendants avoided questions regarding dosage and safety:

[JIM BIRCHENOUGH]...Okay, and then just one the recent combination

data, have you yet seen any of those does-limiting toxicities with the combination with taxol and carbo that you hadn't seen at ASCO and what are your thoughts with regards to the toxicity profile you've seen through Barcelona.

[MICHAEL WICK]: You are at ASCO when you saw the presentation there actually in the dose 1 and Phase 1 presentation, actually much like the Phase 2 that we presented with taxol and carbo. We went the full monodose therapy of TELCYTA, if you recall we saw the CR at 400 milligrams meters, so we continued to treat now substantially more patients were quite pleased with the safety profile. *We are going to explore several doses and we will comment on that at the appropriate time.*

2006

83. Telik announced its fourth quarter and 2005 year end financial results and 2006 financial guidelines on February 9, 2006. The release stated that "2005 highlights included":

- The advancement of our lead product candidate, TELCYTA, in three randomized Phase 3 registration trials and in two Phase 2 trials in first-line non-small cell lung cancer:
 - The ASSIST-1 Phase 3 trial completed enrollment of 440 women with platinum refractory or resistant ovarian cancer in the third-line setting. The primary endpoint for ASSIST-1 is improvement in survival.
 - A peer-reviewed publication describing the Phase 2 TELCYTA trial supporting the ASSIST-1 trial was published in the *International Journal of Gynecological Cancer*.
 - The ASSIST-3 trial was initiated to evaluate the combination of TELCYTA plus carboplatin in second-line platinum refractory or resistant ovarian cancer. This trial is enrolling 244 women. The primary endpoint for ASSIST-3 is objective response rate as well as progression-free survival.
 - The ASSIST-2 trial completed enrollment of 520 patients with platinum resistant non-small cell lung cancer in the third-line treatment setting. Improvement in survival is the primary endpoint of the ASSIST-2 trial.
 - Positive interim data from the multicenter Phase 2 trial of TELCYTA administered in combination with the standard regimen of carboplatin and paclitaxel in the first-line non-small cell lung

cancer were reported at the 11th World Conference on Lung Cancer in July. This trial has been expanded to multiple sites and is intended to enroll approximately 100 patients.

- Positive interim data from the multicenter Phase 2 trial of TELCYTA administered in combination with cisplatin, also in first-line non-small cell lung cancer, were reported at the 41st annual meeting of the American Society of Clinical Oncology and at the 11th World Conference on Lung Cancer.
- Preclinical data demonstrating the ability of TELCYTA to resensitize platinum-resistant human ovarian cancer cells to platinum were reported at the American Association for Cancer Research 96th annual meeting. These data provided scientific rationale for the ASSIST-3 trial design.
- Preclinical data describing the synergistic inhibitory effects of both doublet and triplet combinations of TELCYTA with platinum and taxane drugs as compared to the individual agents in human ovarian and non-small cell lung cancer cells were presented at the American Association of Cancer Research 96th annual meeting. These data provided scientific support for Phase 2 first-line non-small cell lung cancer trials.

84. The Company announced its first quarter financial results for 2006 on May 4, 2006. The release stated that “recent highlights include,” in relevant part:

- Completion of ASSIST-3 enrollment: Telik announced the completion of planned enrollment for the ASSIST-3 trial, a Phase 3 trial evaluating the combination of TELCYTA plus carboplatin to treatment with Doxil in women with platinum refractory or resistant ovarian cancer.
- TELCYTA presentation at the 97th annual meeting of the American Association for Cancer Research: Telik reported positive preclinical results with its lead cancer produce candidate, TELCYTA (TLK286), that support TELCYTA’s unique mechanism of targeted activation in cancer cells and the synergy observed when TELCYTA is administered in combination with platinum-based chemotherapeutic drugs.

85. On August 3, 2006, Telik announced its quarterly financial release, conference call and webcast. The release stated in relevant part that:

- Completion of patient enrollment in the ASSIST-3 Phase 3 clinical trial, which will compare treatment with the combination of TELCYTA and

carboplatin to treatment with liposomal doxorubicin, also in the second line setting women with platinum refractory or resistant ovarian cancer.

86. On September 25, 2006, Telik released an update on ASSIST-1 Status. The release stated that "Telik, Inc. announced today that the pre-specified number of events has been reached on the ASSIST-1 Phase 3 trial in platinum refractory or resistant ovarian cancer."

87. On December 12, 2006, Telik issued a release entitled "Telik Reports Preliminary Results on ASSIST-1, ASSIST-2 and ASSIST-3 Phase 3 Clinical Trials," which disclosed the failure of all three arms of the TELCYTA trials. The release stated in relevant part:

Non-Small Cell Lung Cancer

ASSIST-2 Trial

The ASSIST-2 trial, a 520 patient multinational, randomized study designed to evaluate TELCYTA as compared to gefitinib in the third-line therapy of advanced non-small cell lung cancer, *did not achieve a statistically significant improvement in overall survival, the primary endpoint.*

Platinum Refractory or Resistant Ovarian Cancer

ASSIST-1 Trial

The ASSIST-1 trial, a 440 patient multinational, randomized study designed to evaluate TELCYTA as compared to the active control agents liposomal doxorubicin or topotecan in the third-line therapy of platinum resistant ovarian cancer, *did not achieve its primary endpoint of demonstrating a statistically significant improvement in overall survival for TELCYTA as compared to the active controls. While the preliminary analysis revealed a number of internal inconsistencies that need to be further investigated, resolution of these inconsistencies may not change the preliminary results.*

ASSIST-3 Trial

The ASSIST-3 trial, a 244 patient randomized trial conducted in the U.S., was designed to demonstrate a statistically significant improvement in overall tumor response to the combination of TELCYTA plus carboplatin compared to liposomal doxorubicin in the second-line treatment of platinum resistant ovarian cancer. Under the trial protocol, patients were to have received treatment until tumor progression or unacceptable toxicity. However, a major discordance was

observed between the clinical review of the tumor scans and the independent radiology review. *Approximately 25% of the patients were discontinued prematurely from the assigned study treatment as judged by the independent review of the scans. Therefore, the company believes the trial was compromised and may not be suitable for a regulatory submission.* The company plans to meet with advisors to review the results and also to determine if any changes should be made to the protocol and/or trial conduct procedures for the ongoing ASSIST-5 trial.

2007

88. Telik issued a release on April 17, 2007 entitled "Telik Reports Positive Data Demonstrating Synergy in Combination and Highly Statistically Significant Effect of TELCYTA as Maintenance Therapy in First-Line Non-Small Cell Lung Cancer." The release stated in relevant part:

Telik, Inc. announced the presentation today of results from a Phase 2 clinical trial of the triplet combination of TELCYTA (TLK286), carboplatin and paclitaxel in the first-line treatment of advanced non-small cell lung cancer. *The results include highly statistically and clinically significant improvement in both progression-free survival and overall survival in responding patients who received TELCYTA maintenance therapy as compared with those who did not receive TELCYTA maintenance therapy.* The data were presented at the 98th annual meeting of the American Association for Cancer Research (AACR) in Los Angeles.

* * *

The triplet combination was generally well-tolerated at all TELCYTA doses evaluated, with toxicities similar to those expected with each drug alone. There were no new, unexpected or cumulative toxicities. TELCYTA maintenance therapy was, as expected, well-tolerated, with Grade 1 or 2 toxicities observed in fewer than 5% of patients.

"Many approaches to maintenance therapy following first-line treatment for advanced non-small cell lung and ovarian cancer have been evaluated, with most adding little to efficacy while exposing patients to ongoing risks from toxic chemotherapy," said Gail L. Brown, M.D., senior vice president and chief medical officer. "The safety profile and clinical activity of TELCYTA, both in combination with carboplatin and paclitaxel and as monotherapy, suggest a potential role for this investigational agent as part of first-line combination treatment and as single agent maintenance therapy of non-small cell lung cancer. We will review these results with our expert advisors to discuss plans to expeditiously advance the TELCYTA program toward registration."

89. On May 3, 2007, the Company announced its first quarter financial results for 2007. The release stated that “Telik also reviewed data presented at the recent American Association for Cancer Research (AACR) 98th annual meeting”:

- Positive data were reported from a multicenter Phase 2 trial of TELCYTA in combination with carboplatin and paclitaxel in the first-line treatment of advanced non-small cell lung cancer. One hundred twenty-nine patients were enrolled for a planned four to six cycles of triplet combination therapy, followed by optional TELCYTA maintenance therapy for those patients with ongoing clinical benefit (objective response or stable disease) at the completion of combination therapy. In the intent-to-treat population, the objective response rate was 34.1% and the overall disease stabilization rate was 77.5%. The median progression-free survival was 4.9 months and median survival was 9.6 months.
- Of the 100 patients (77.5%) with objective response or stable disease, 50 patients received TELCYTA maintenance therapy and 50 patients did not receive TELCYTA maintenance therapy. The two groups were well-balanced for patient demographics, key non-small cell lung cancer disease characteristics and prognostic factors, except for ECOG performance status, which favored the non-maintenance group. Median progression-free survival in the patients receiving TELCYTA maintenance therapy was 6.9 months, compared with 4.2 months in those not receiving TELCYTA maintenance therapy. ($p < 0.0001$, HR 0.36). Median survival in the TELCYTA maintenance group was 14.2 months compared with 8.4 months in those not receiving TELCYTA maintenance therapy ($p = 0.0003$, HR 0.40). Outcomes were similar whether the patients had objective tumor response or stable disease.
- A series of preclinical studies focused on the cellular and molecular correlates of synergistic cancer cell growth inhibition by TELCYTA, carboplatin and paclitaxel alone and in different combinations in human lung cancer cells. *These studies support the Phase 2 trial of TELCYTA in combination with carboplatin and paclitaxel reported at the AACR meeting.*
- A separate series of preclinical studies evaluated the anti-angiogenic effects of TELCYTA with and without bevacizumab, demonstrating that TELCYTA can potentially be a potent inhibitor of human endothelial cell proliferation. Further, the combination of TELCYTA and bevacizumab produced significantly enhanced inhibition of endothelial cell proliferation and capillary tubule formation. *These studies suggest the potential for*

TELCYTA use in combination with bevacizumab and other anti-angiogenic agents.

90. At the annual ASCO meeting on June 3, 2007, Telik finally released the data underlying the results of its ASSIST-1, 2 and 3 clinical trials for TELCYTA. While the Company had disclosed on December 26, 2006 that ASSIST-1 had failed to show that TELCYTA could improve the overall survival of women with advanced ovarian cancer compared to currently approved drugs, Defendants did not disclose the true results of the trial. In fact, Defendants concealed these results for over five months. In actuality, women treated with TELCYTA *died more than five months faster on the drug than off of it*. In the control arm of the study where women were treated with the approved drugs doxorubicin or topotecan, the women showed a median survival time of 13.6 months. The negative survival effect of TELCYTA was statistically significant. It was TELCYTA, not random chance, which caused these women to die faster.

91. On June 3, 2007, Telik disclosed that a Phase III study of TELCYTA in non-small cell lung-cancer patients also resulted in a negative survival effect of one and a half months. In this study, ASSIST-3, TELCYTA patients had a reported median survival time of 4.6 months compared to a median survival time of 6.1 months for patients in the control arm.

92. After the close of trading on June 4, 2007, Telik announced that the FDA had placed a clinical hold on the IND application for TELCYTA. The FDA initiated this hold after the Company presented the clinical trial results at the annual meeting of the American Society of Clinical Oncology. Simultaneously, Telik stated that no new patients would be enrolled on TELCYTA clinical trials, and that no patients currently being treated on the trials would receive additional treatment until the FDA released the clinical hold.

93. The false and misleading statements made during the Class Period regarding TELCYTA's efficacy and safety artificially inflated the Company's stock price. After the Company revealed on December 26, 2006 that TELCYTA had failed in all three arms of its clinical testing, the Company's stock plunged in a single trading session from over \$16 per share to below \$5 per share. This was a drop of 70%.

94. Telik's stock price fell further following the Company's disclosures on June 3, 2007 whereby Telik disclosed that the ovarian cancer arm of the TELCYTA trials failed with Telik again disclosing that the results had been compromised and subjects were improperly released early, tainting the data. Following this announcement, Telik's share price dropped by 20%.

95. When the news that the FDA had ordered Telik to halt the clinical trials of TELCYTA reached the market after hours on June 4, 2007, the Company's stock price fell nearly 30%.

96. Telik's stock traded at inflated levels during the Class Period as a result of Defendant's false and misleading statements and omissions regarding the safety and efficacy of TELCYTA. The stock traded as high as \$29.04 per share by April of 2004, whereby the Company sold over \$322 million worth of Telik securities in two underwritten public stock offerings.

DEFENDANTS ACTED WITH SCIENTER

97. Each Individual Defendant had knowledge of Telik's problems and was motivated to conceal such problems. Defendants Wick and Butitta, as CEO and CFO, were responsible for the reports and claims relating to TELCYTA as well as the press releases issued by the Company. Each Individual Defendant sought to demonstrate that he or she could lead the Company successfully and generate the successful commercialization of TELCYTA, including obtaining FDA approval, and was motivated to engage in the fraudulent practices alleged herein in order to obtain cash and stock bonuses, collectively worth tens of millions of dollars.

LOSS CAUSATION ALLEGATIONS

98. Telik common stock was publicly traded in an efficient market at all relevant times. As described, *supra*, Defendants' material misrepresentations and omissions had the effect of creating and maintaining artificially inflated prices for Telik securities. The continued misrepresentations regarding TELCYTA's safety, efficacy and commercial viability served to maintain Telik's share price at artificially inflated levels during the Class Period.

99. Defendants had a duty to promptly disseminate accurate and truthful information with respect to TELCYTA's clinical trial results, or to cause and direct that such information be disseminated, and to promptly correct any previously disseminated information that was misleading to the market. As a result of their failure to do so, the price of Telik's common stock was artificially inflated during the Class Period, damaging Plaintiff and the Class.

100. Until shortly before Plaintiff filed this Complaint, he was unaware of all of the facts, as described herein, and could not have reasonably discovered the Defendants' fraudulent scheme by the exercise of reasonable diligence.

101. Defendants' false and misleading statements and omissions in their press releases and other public statements directly caused the losses of the Plaintiff Class. On the strength of these false statements, misrepresentations and material omissions, the Company's stock was artificially inflated during the Class Period.

102. The timing and magnitude of the decline in the value of Telik's stock price negates any inference that the loss suffered by Plaintiff and the Class was the result of factors unrelated to Defendants' fraudulent conduct.

FRAUD ON THE MARKET ALLEGATIONS

103. At all relevant times, the market for Telik securities was an efficient market for the following reasons, among others:

- i. At all relevant times during the Class Period, Telik's common stock was listed and actively traded either over the counter or on the Nasdaq, a highly efficient national market.
- ii. As a registered and regulated issuer of securities, Telik filed periodic reports with the SEC, in addition to the frequent voluntary dissemination of information described in this Complaint.
- iii. Numerous financial analysts followed the Company's stock. Thus, the Company's stock reflected the effect of information disseminated in the market.

104. As a result of the above, the market for Telik securities promptly digested current information with respect to the Company from all publicly available sources and reflected such information in the securities' prices. Under these circumstances, all purchasers of Telik securities during the Class Period suffered similar injury through their purchase of securities at prices which were artificially inflated by Defendants' misrepresentations and omissions. Thus, a presumption of reliance applies.

INAPPLICABILITY OF STATUTORY SAFE HARBOR

105. The statutory safe harbor for certain forward-looking statements does not apply to the misrepresentations and omissions alleged in this complaint. Many of the statements were not specifically identified as "forward-looking statements" when made. To the extent that there were any properly identified forward-looking statements, there were no meaningful cautionary statements identifying the important, then-present factors that could and did cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are nonetheless liable because at the time each of the misrepresentations was made, the particular speakers knew that the statement was false or misleading at that time.

106. Any warnings or other cautionary language contained in the press releases and other public statements described herein were generic, “boilerplate” statements of risk that would affect any similar company, and misleadingly contained no factual disclosure of any of the problems with the Company which placed the ability of the Company to accurately depict its own financial situations into serious question. As such, any forward-looking statements complained of herein were not accompanied by meaningful cautionary language.

107. Any relevant purported risk disclosures were, in fact, *false and misleading* in and of themselves, by virtue of the fact that the events which the risk disclosures purported to warn against as contingencies had frequently already become a reality or a certainty.

CLAIMS FOR RELIEF

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

108. Plaintiff incorporates by reference and realleges all preceding paragraphs as though fully set forth herein.

109. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or *should have known* were misleading. The statements contained misrepresentations and failed to disclose material facts necessary in order to make them, in light of the circumstance under which they were made, not misleading.

110. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they:

- i. employed devices, schemes and artifices to defraud;

- ii. made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- iii. engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Telik common stock during the Class Period.

111. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Telik common stock. Plaintiff and the Class would not have purchased Telik common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

112. As a direct and proximate result of these Defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Telik common stock during the Class Period.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

113. Plaintiff incorporates by reference and realleges all preceding paragraphs as though fully set forth herein.

114. The Individual Defendants acted as controlling persons of Telik within the meaning of §20(a) of the Exchange Act. By reason of their position with the Company and their ownership of Telik common stock, the Individual Defendants had the power and authority to cause Telik to engage in the wrongful conduct complained of herein. Telik controlled the Individual Defendants and all of its employees. By reason of such conduct, the Individual Defendants and Telik are liable pursuant to §20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;
- B. Awarding plaintiff and the members of the Class damages, interest and costs;
- C. Awarding Plaintiff reasonable costs and attorneys' fees; and
- D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: August 6, 2007

Respectfully submitted,



Christopher J. Keller (CK-2347)
Andrei V. Rado (AR-3724)
Alan Ellman (AE-7347)
LABATON SUCHAROW &
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Proposed Lead Counsel

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

STEPHEN O'GRADY, on behalf of Himself and all others similarly situated,)	CIVIL ACTION
)	
)	
Plaintiff,)	
v.)	CERTIFICATE OF
)	SERVICE
TELIK INC., MICHAEL M. WICK, and)	
CYNTHIA M. BUTTITA,)	
)	
Defendants.)	
)	
)	
)	
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)	

CERTIFICATE OF SERVICE

I, Alan I. Ellman, hereby certify that a true and correct copy of the Complaint served via U.S. Mail to the counsel listed below:

COUNSEL FOR DEFENDANTS

Jack C. Auspitz
Jamie A. Levitt
MORRISON & FOERSTER
1290 Avenue of the Americas
New York, NY 10104

David W. Haller
Linda C. Goldstein
COVINGTON & BURLING LLP
620 Eighth Avenue
New York, NY 10018

Dated: August 6, 2007

A handwritten signature in black ink, appearing to read 'A. I. Ellman', written over a horizontal line.

Alan I. Ellman

Exhibit A

PLAINTIFF CERTIFICATION

I, Stephen O'Grady, hereby declare that:

1. I have reviewed a draft Complaint in this class action and have authorized the filing thereof.
2. I did not purchase (or otherwise acquire) or sell securities of Telik, Inc. the subject of the Complaint, at the direction of my counsel or in the hope to participate in any private action arising under the Securities Act of 1933 or the Securities Exchange Act of 1934.
3. I am willing to serve as a representative plaintiff on behalf of the class defined in the Complaint, including providing testimony at deposition and trial, if necessary.
4. I have engaged in the following transactions involving the securities of Telik, Inc.:

<u>Purchases</u>	<u>Trade Date</u>	<u>Price Per Security</u>	<u>Total</u>
2000 Shares	12/8/2006	17.03	34,052.45
1000 Shares	12/18/2006	16.86	16,859.40
800 Shares	12/22/2006	16.09	12,872.00
			<u>63,783.85</u>

<u>Sales</u>	<u>Date</u>	<u>Price Per Security</u>	<u>Total</u>
3800 Shares	12/26/2006	4.81	18,281.80

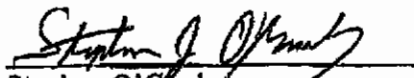
5. During the last three years preceding the date of this Certification, I have sought to serve as a representative plaintiff on behalf of a class in the following actions brought under the Securities Act of 1933 or the Securities Exchange Act of 1934: *N/A*

6. I will not accept any payment for serving as a representative plaintiff on behalf of the class beyond my pro rata share of any recovery, except as ordered by the Court.

7. Nothing herein shall be construed to be or constitute a waiver of my attorney-client privilege.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on the 3rd day of August, 2007.


Stephen O'Grady